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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,254	10/11/2001	King Chuen Li	TAR.06	9603

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/976,254	Applicant(s) LI ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,13,14,23,24,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,13,14,23,24,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 3/18/04 wherein claims 3, 4, 9-12, 15-22, 25, 26, and 29-32 were canceled.

Note: Claims 1, 2, 5-8, 13, 14, 23, 24, 27, and 28 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 3/18/04 to the rejection of claims 1, 2, 5-8, 13, 14, 23, 24, 27, and 28 made by the Examiner under 35 USC 102, 103, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting Rejections

I. The provisional rejection of claims 1, 2, 5, 6, 8, 13, 23, and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14, 16-19, 26, 27, and 29 of copending application number 10/093,845 is MAINTAINED for reasons of record in the office action mailed 9/16/03.

II. The provisional rejection of claims 1, 2, 5-7, 13, and 23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 10, 11, and 39 of copending application number 10/158,777 is MAINTAINED for reasons of record in the office action mailed 9/16/03.

Note: It is duly noted that Applicant intends to submit a terminal disclaimer over 10/158,777 and 10/093,845 when the claims are indicated as allowable.

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112 Rejections

The 112 rejections are WITHDRAWN for reasons of record in Applicant's response.

102 Rejections

The 102 rejections are WITHDRAWN for reasons of record in Applicant's response.

103 Rejections

The 103 rejections are WITHDRAWN for reasons of record in Applicant's response.

NEW GROUNDS OF REJECTION

103 Rejections

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 5-8, 14, 23, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (US 2002/0044919).

Yu discloses method and compositions for treating neoplasms, tumors, and cancers wherein a composition comprising one or more haptens and coagulation agents alone or in combination with other anti-neoplastic agents are administered (see entire

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document, especially, abstract, page 1, paragraphs [0009] and [0010]). The composition may be used for various neoplasms, tumors, and cancers (page 2, paragraph [0012]). The composition combinations provide improved therapeutic effectiveness of cancer therapy to most cancer patients to which they are administered. Each composition component may be a separated composition or combined (page 2, paragraphs [0013] and [0014]). The combinations may include other agents such as anti-cancer therapeutics, radiosensitizers, and anti-angiogenic agents. (page 2, paragraph [0022]). Possible anti-angiogenic agents include LM609 and Vitaxin (page 3, paragraph [0024]; page 12, paragraph [0143]). The treatment using the composition of Yu may be used in conjunction with other cancer therapies (i.e., surgery, radiation therapy, chemotherapy, and traditional immunotherapy) [page 5, paragraph [0059]. The hapten is an antibody specific substance (page 6, paragraph [0073]). Various anti-neoplasm agents may be used alone or in combination with other composition components (page 6, paragraph [0078]). A facilitating agent is a molecule that facilitates conjugation between the hapten and tumor antigen may be used. The purpose of such agent is to link the hapten to the tumor antigen or facilitate such linkage (page 7, paragraph [0088]). The facilitating agent is preferably a chelator or chemical linking agent wherein the chelator may comprise a lysine residue (page 17, paragraph 0165]). In Table 2, page 12 (and page 12, paragraph [0143]), it is disclosed that $\alpha v \beta 3$ integrins may be used for inhibition of cell adhesion. Any neoplasm, tumor, or cancer may be treated using the composition of Yu (page 19, paragraph [0188]; page 20, paragraph [0189]). Thus, while Yu may not disclose a single composition comprising Applicant's

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composition components, the reference does disclose that each of Applicant's composition components may be used alone or in combination with one another.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a therapeutic composition and uses thereof wherein the composition comprises a targeting moiety, a linking group, and a therapeutic moiety because Yu disclose therapeutic agents and uses thereof comprising one or more haptens in combination with anti-neoplastic agents. Thus, both Applicant and Yu disclose compositions and uses thereof comprising a therapeutic moiety (i.e., an anti-neoplastic agent), a linking group (i.e., a facilitating agent), and a targeting agent (i.e., a hapten such as Vitaxin or LM609).

5. Claims 1, 2, 5-7, 13, 14, 23, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness et al (US Patent No. 6,261,537)

Klaveness et al disclose diagnostic and therapeutic agents that may be coupled to one or more vectors (see entire document, especially, abstract). In addition, Klaveness et al disclose (1) the agents comprise a targeting moiety (column 1, lines 52-64) that is capable of binding a vector. (2) The vector is attached or linked to the reporter moiety using various moieties which include polylysine chains (columns 1-2, bridging paragraph; column 10, lines 17-47). Possible linking agents include PEG components and polylysine (column 17, lines 61-68; column 19, lines 3-27). (3) The vector is usually an antibody which may be administered alone, subsequent to the reporter, or coupled to a moiety that is capable of specifically binding the pretargeting vector molecule (column 9, lines 6-31; column 13, lines 58-68). (4) The agents of

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Klaveness et al may be used in the formation of new blood vessels (neovascularization) [column 12, lines 50-53]. (5) The therapeutic agents may be delivered to diseased or necrotic areas of, for example, the heart, liver, spleen, vasculature, or kidneys. An antibody may be used as the vector (column 23, lines 9-34). Possible vectors include ICAM-1 and $\alpha v \beta 3$ (column 24, line 51; column 25, line 58).

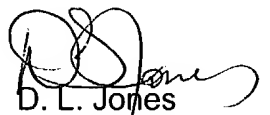
Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a therapeutic composition and use thereof wherein the composition comprises a targeting moiety, a linking carrier, and a therapeutic moiety because Klaveness et al disclose therapeutic agents that are linked to at least one vector as set forth above. Thus, both Applicant and Klaveness et al disclose compositions comprising a therapeutic moiety, a linking group, and a targeting moiety.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

June 24, 2004